



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/226,875	04/13/94	AKAZAWA	P94458US

15M1/1103

LAWRENCE A. STEWARD
BAKER & DANIELS
300 N MERIDIAN ST.
SUITE 2700
INDIANAPOLIS, IN 46204

PHELAN, D. EXAMINER

ART UNIT PAPER NUMBER

1502

5

DATE SENT: 11/03/94

This is a copy of the communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-4 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-4 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Art Unit: 1502

Part III DETAILED ACTION

Acknowledgement is made of the Priority Paper filed April 13, 1994, Preliminary Amendment A, filed May 17, 1994 and the Information Disclosure Statement filed July 15, 1994.

Claim Rejections - 35 USC § 112

1. Claims 1, 3 and 4 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to an external plaster preparation as described in claims 1, 3 and 4, wherein the cyclic organic base is defined as hydroxyethyl pyrrolidine or hydroxyethylpiperidine. The specification, on page 4, lines 14-23, identifies hydroxyethylpyrrolidine and hydroxyethylpiperidine as the cyclic organic base used in the invention. These two components embody Applicant's scope of enablement as no other compounds are suggested. See M.P.E.P. §§ 706.03(n) and 706.03(z).

2. Claims 1-4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the use of the phrases "general" and "such as". It is suggested to simply delete "general" at all occurrences in all claims. Further, the phrase "such as"

Art Unit: 1502

renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention or not, and the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. It is suggested to replace "such as" with "comprising" at all occurrences in all claims.

It is further suggested to amend claim 1, penultimate line, by deleting "and also" and inserting "wherein".

Claim 4 is indefinite in referring to "the above mentioned diclofenac". It is suggested to amend by inserting in claim 4, line 2, after "plaster preparation" (but before the comma) "according to claim 1". It is further suggested to actually define X and n and to delete "as defined above"

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

Art Unit: 1502

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

5. Claims 1-4 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Ziggiotti (USPN 4,948,805). Ziggiotti discloses a preparation comprising diclofenac salt with a cyclic organic base, which base is hydroxyethylpyrrolidine (col 1, l 34-47) and claims 1-4. Excipients comprising buffers, preservatives, etc. may be present (col 2, l 40-48). A method of producing comprising mixing the components is also disclosed (col 2, l 66 through col 3, l 18). Ziggiotti does not disclose an external plaster. However, to the extent that the present claims lack definition of the plaster or support, it is the position of the Examiner that Ziggiotti anticipates present claims 1-4.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Gabrielle Phelan, Ph.D. whose telephone number is (703) 308-0756. The Examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Thurman Page, can be

Serial Number: 08226875

-5-

Art Unit: 1502

reached on (703)-308-2927. The fax phone number for this Group is (703)-305-3596.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)-308-2351.

dgp
October 25, 1994


D. GABRIELLE PHELAN, PhD
PRIMARY EXAMINER
GROUP 1500